In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0947V

ANTONIO J. SMITH, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: May 28, 2024

Scott B. Taylor, Urban & Taylor, S.C., Milwaukee, WI, for Petitioner.

Tyler King, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT – SPECIAL PROCESSING UNIT[1]

On February 18, 2021, Antonio J. Smith filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that he suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to him on November 5, 2019. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU"). For the following reasons, I find that Petitioner has preponderantly established all requirements for entitlement to compensation for a Table SIRVA.

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Almost two years after the claim's initiation, Respondent filed a Rule 4(c) Report recommending denial of entitlement to compensation for a Table SIRVA. Rule 4(c) Report (ECF No. 29) at 7 – 8. The parties thereafter submitted briefing in anticipation of my ruling on the record. *See* Scheduling Order filed Apr. 27, 2023 (ECF No. 30); Memorandum filed June 11, 2023 (ECF No. 32) ("Brief"); Response filed Aug. 9, 2023 (ECF No. 34); Reply filed Aug. 11, 2023 (ECF No. 35). The matter is now ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Evidence

I have reviewed all of the filings submitted by both parties to date, but limit discussion to the issues requiring adjudication.

- Petitioner was born in 1981. For over three years prior to the date of vaccination and for at least several years thereafter, he has been in the custody of the Wisconsin Department of Corrections, and specifically incarcerated at the Wisconsin Secure Program Facility. *See generally* Exs. 3 – 8 (certified medical records); *but see, e.g.*, Ex. 4 at 293 – 95 (transfer off-site for urgent medical attention); *see also* Ex. 9.[4]

- A single nursing note from April 2019 suggests that Petitioner suffered from neck pain. Ex. 4 at 18. But this condition is not corroborated by any physical examination or diagnosis involving the neck. *Id.* at 18 – 19. Instead, the majority of medical records reflect that Petitioner's pain was in his lower back, extending down his left leg. *See, e.g.*, Ex. 4 at 17, 19, 22, 24, 34, 64, 65. This pain was chronic – attributed both to sciatica, Ex.4 at 122, 125, and to a previous motor vehicle crash, *id.* at 262.[5] However, the lower back pain was not definitively diagnosed; electrodiagnostic studies, as well as x-rays of his spine, were unremarkable. Ex. 4 at 65 – 67, 71.

- Petitioner received the subject flu vaccine in his left deltoid on November 5, 2019. Ex. 3 at 53, 258 – 59. Later that same day, Petitioner submitted two separate health service requests ("HSRs") concerning vaccination site pain. Ex. 3 at 14 – 15.

- On November 6, 2019, a nurse observed that Petitioner's left arm was slightly swollen. She discussed that injection site pain was common and could be managed conservatively. Ex. 3 at 32 – 34; *but see id.* at 311, 314 – 15 (Petitioner's subsequent HSRs, reporting continued pain).

[4] The information contained in Ex. 9 is publicly available from the Wisconsin Department of Corrections, *Offender Locator Public*, https://appsdoc.wi.gov/lop/details/detail (search for Antonio J. Smith, birth year 1981, last accessed May 24, 2024).

[5] Respondent requested any additional "records or documentation relating to Petitioner's back pain and the motor vehicle accident." Rule 4(c) Report at 3, n. 1. Based on Petitioner's production of certified medical records for over three years prior to the date of vaccination as well as his incarceration, I have concluded that the evidence is sufficiently complete, and that further efforts to satisfy Respondent's request are unlikely to yield additional relevant information.

- On November 12, 2019, a nurse observed that Petitioner was still suffering from left shoulder pain, and therefore refused to submit to physical examination. Ex. 3 at 30 – 32.

- On November 13, 2019, Eileen Gavin, M.D., similarly documented Petitioner's history of a left shoulder injury since the flu vaccine, ongoing pain, and refusal of physical examination. Ex. 3 at 18. Dr. Gavin questioned why a vaccination "would affect the bony shoulder girdle," and whether Petitioner "may have had a pre-existing shoulder problem that was made worse by the increased inflammation." *Id.* "Regardless, [Dr. Gavin] discussed with him at great length the importance of range of motion ["ROM"] exercises before it becomes frozen." *Id.*

- A December 16, 2019, PT initial evaluation noted Petitioner's history of: "[p]ain in left shoulder since he received his flu vaccination on 11/5/2019. He was unable to move his hand, elbow, and shoulder L UE at first… He is still having a lot of pain and stiffness in the shoulder." Ex. 3 at 66. An exam confirmed left-sided weakness, decreased ROM, and "frozen shoulder." *Id.* at 66 – 72. On January 8, 2020, after attending six formal sessions and displaying "slow progress," Petitioner was discharged with a home exercise program. *Id.*

- On March 4, 2020, Tricia Lorenz, D.O., assessed Petitioner with tendinitis and impingement syndrome. Ex. 3 at 19 – 20.

- On June 25, 2020, Michael Gross, M.D., recorded that the Pandemic had interrupted formal treatment for Petitioner's left shoulder; he was not following his HEP due to pain, and he currently had decreased ROM. Ex. 3 at 34 – 35. Dr. Gross repeated the assessment of tendinitis and impingement syndrome, and obtained an x-ray of the shoulder with unremarkable findings. *Id.* at 34 – 35, 76.

- On July 30, 2020, Petitioner resumed formal PT for his left shoulder – again, relating the injury to his flu vaccination. Ex. 5 at 104. On exam, the left shoulder was painful and ROM was "grossly impaired." *Id.* at 105. The physical therapist assessed adhesive capsulitis in the "freezing stage," which would likely be followed by "frozen" and "thawing" stages. *Id.*

- Subsequent medical records reflect that Petitioner was motivated to avoid any injections or surgery. He adhered to a daily HEP in between periodic PT sessions (occurring approximately once per month), improved his ROM, but suffered ongoing pain – which was "typical for adhesive capsulitis" according to his physical therapist. Ex. 5 at 98, 100, 102.

- On September 25, 2020, Petitioner was transported off-site for evaluation with Edward Riley, M.D., an orthopedic surgeon at the Gunderson Health System. Ex. 5 at 114. Dr. Gunderson recorded Petitioner's history of left arm pain following the flu shot, as well as a current "painful knot in the left back of his neck." *Id.* at 115. On exam, the left shoulder had decreased ROM, weakness, and normal neurological findings (deep tendon reflexes and sensation). *Id.* There was also "Moderate limitation of neck motion; extension and rotation to left causes pain left neck." *Id.* Dr. Riley's assessment was "stiff left shoulder, left upper extremity weakness." *Id.*

- A January 27, 2021 MRI of Petitioner's left shoulder visualized supraspinatus tendinosis and mild acromioclavicular osteoarthritis. Ex. 5 at 110. That same day, an MRI of his cervical spine visualized degenerative changes and moderate left-sided foraminal narrowing at C5-6 and C6-7. *Id.* at 109.

- At a February 25, 2021, PT session, Petitioner's "fear/ avoidance limits his ability to range [sic? raise?] his shoulder." Ex. 5 at 92. However, his ROM was objectively improved, and he was no longer suffering from adhesive capsulitis. *Id.* The physical therapist questioned whether the MRI findings at C5-7 were causing his ongoing pain. *Id.*

- At an April 8, 2021, PT session, the "pain location" was changed from "shoulder" to "neck." Ex. 5 at 88. Petitioner complained of "similar levels of pain in all joints (left shoulder, neck, and back)." *Id.* at 90. His left shoulder had full strength, full active ROM, and somewhat limited – but "functional" passive external and internal rotation. *Id.* The therapist added: "Deep cervical flexor strength is normal; however, hypertrophy of muscle tissue takes 12 – 16 weeks." *Id.* Petitioner was discharged from formal PT on that date. *Id.*

- Over five months later, in September 2021, Petitioner mentioned "ongoing left shoulder pain" – in addition to low back pain - to James Murphy M.D. Ex. 6 at 20 – 21.

- Petitioner attended formal PT addressing both his left shoulder and low back on October 18, November 16, and December 18, 2021. Ex. 6 at 78 – 92.

- In January 2022, the correctional facility nurses and physical therapist asked Justin Ribault, M.D. to assist with Petitioner's ongoing complaints. Ex. 6 at 51 – 54.

- On February 1, 2022, Dr. Ribault's examination of Petitioner found "limited left neck rotation, limited left shoulder abduction, poor internal rotation; left trap palpation produces pain." Ex. 6 at 17. Dr. Ribault also wrote:

> [Petitioner] has had a stable left shoulder decreased range of motion along with localized pain since at least '18. A 1/2021 MRI showed a supraspinatus tendinosis which would not correlate with his inability to internally rotate his arm. Also per that MRI, he has evidence of a left cervical radiculopathy, but his pain complaint seems to be focused at the rotator cuff and did not correlate with a C5/C6 radiculopathic pattern. His left trapezius is strained which makes sense as it involves the neck and shoulder."

Id. Dr. Ribault also wrote that the shoulder complaint did not "totally matc[h] noted MRI abnormalities," and ordered a Theraband to aid Petitioner's home exercises. Ex. 5 at 18; *accord id.* at 52 (therapist's suggestion of the Theraband).

- Petitioner attended formal PT addressing his left shoulder and low back on April 21, June 16, and July 14, 2022. Ex. 7 at 43 – 49; Ex. 8 at 44 - 47.

- On July 1, 2022, Shirly Godiwalla, M.D., determined that Petitioner's left shoulder and low back pain warranted another off-site consultation – which was postponed several times. Ex. 8 at 23 – 30, 48.

- Finally on November 4, 2022, the off-site orthopedic surgeon Dr. Riley re-evaluated Petitioner – starting with his history of "left shoulder pain and stiffness since a flu shot in November 2019… better than it was but still stiff and painful," while also noting the exercises provided for Petitioner's neck. Ex. 8 at 49. Dr. Riley reviewed the MRIs obtained since their last appointment. *Id.* His assessment was: "Cervical spondylosis with multilevel nerve root impingement and exam c/w left UE weakness. Chronic left shoulder pain and limited motion. Could be sequela of frozen shoulder." *Id.* Dr. Riley "recommended that [Petitioner] be evaluated for his left UE weakness before proceeding with any treatment of his left shoulder. This could be via referral to neck specialist or possibly EMG. Neck situation needs to be clarified before settling on treatment plan for shoulder. Treatment of the shoulder itself could be trial cortisone injection or arthroscopic eval." *Id.*

- On November 9, 2022, Petitioner complained again of left shoulder pain. Ex. 8 at 27. A nurse advised that he was being scheduled for an off-site pain management consultation. *Id.* However, no further records have been filed.

IV. Findings of Fact

A. Prior History

The first issue to be resolved is whether Petitioner had "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection," 42 C.F.R. § 100.3(c)(10)(i).

In disputing Petitioner's satisfaction of the above criterion, Respondent first cites evidence of "pre-existing complaints of pain throughout [Petitioner's] back and neck." Rule 4(c) Report at 8. But Petitioner argues that this characterization is overly broad – because any prior complaints were mostly related to his lower back (which has no correlation to his left shoulder at all), with only one complaint about neck pain. Brief at 5. Respondent did not rebut Petitioner's explanation, which is confirmed by an independent review of the medical records (as set forth above). And importantly, neither the medical records themselves nor Respondent's position addresses how any such prior history "would explain" the post-vaccination complaints.

Respondent also emphasizes Dr. Ribault's medical record notation that Petitioner's left shoulder pain and decreased ROM had been present "since at least '18." Ex. 6 at 17. Respondent maintains that "this would predate Petitioner's influenza vaccination," Rule 4(c) Report at 8, and emphasizes that Petitioner has the burden of establishing that this history is inaccurate. Response at 3.

While Dr. Ribault's notation "warrant[s] consideration as trustworthy evidence," Response at 3 (citing *Cucuras*, 993 F.2d 1525, 1528), it was also created in February 2022 – several years after both the vaccination and the even earlier timeframe it references. Dr. Ribault did not appear to have any previous patient relationship with Petitioner, and it is not evident he had reviewed any prior medical records prior to their first meeting. The available evidence establishes only that Dr. Ribault was fulfilling other medical providers' requests for assistance in determining, and prescribing, appropriate pain measures for Petitioner. Moreover, (and as Petitioner persuasively notes), "[i]nconsistency among medical records… alone does not defeat a claim unless it *preponderantly supports* an alternative finding." *Graczyk v. Sec'y of Health & Hum. Servs.*, No. 21-0376V, 2023 WL 4573868, at *6 (Fed. Cl. Spec. Mstr. Jun. 16, 2023) (emphasis added). Here, Dr. Ribault's one inconsistent record is outweighed by the overall weight of medical records, which do not document any pre-vaccination left shoulder complaints. Therefore, preponderant evidence supports the determination that

Petitioner did not likely have any history of left shoulder pain, inflammation, or dysfunction prior to the November 5, 2019, vaccination.

Based on the above factual findings, Petitioner has preponderantly established this Table element.

B. Other Condition or Abnormality

Petitioner also has the burden of establishing that "no other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy). 42 C.F.R. § 100.3(c)(10)(iv).

On this point, Respondent emphasizes Dr. Ribault's February 2022 assessment of a left trapezius strain. Rule 4(c) Report at 8, citing Ex. 6 at 17. But Petitioner disputes that any such strain had been present and undiagnosed for over two years. Brief at 5. Indeed, Dr. Ribault "does not state when Petitioner's trapezius strain occurred or how it happened." Reply at 6. Petitioner emphasizes the documentation from earlier, and much closer in time to the November 2019 vaccination, of acute left shoulder pain, supraspinatus tendinopathy, impingement syndrome, and adhesive capsulitis. *Id.* at 7 – 8. Indeed, all of the above is documented well before any significant neck pain, which is first documented in or around September 2020. *See* Ex. 5 at 114 – 15.

Overall, there is far less than preponderant evidence that the trapezius strain would explain Petitioner's symptoms. Thus, this element is also met.

Conclusion and Scheduling Order

Based on a full review of the record and the lack of any further objections from Respondent, I also conclude that Petitioner has established preponderant evidence of all other required criteria for SIRVA as defined by the Vaccine Injury Table, and for all other legal prerequisites for compensation under the Vaccine Act (as set forth in the above legal standard). Thus, Petitioner is entitled to compensation for a Table SIRVA.

Petitioner previously reported that his claim did not involve a Medicaid lien. Scheduling Order filed Nov. 12, 2021. He also conveyed a settlement demand limited to pain and suffering. Status Report filed Mar. 1, 2022 (ECF No. 21).

As the case proceeds to the damages phase, my preliminary and tentative assessment is that the SIRVA damages picture extends at least until the April 8, 2021, PT discharge. The subsequent medical records are less clear as to whether Petitioner was still suffering from a SIRVA, versus more compensatory or entirely unrelated pain in other parts of his body which would be harder to include in the SIRVA damages picture. It is also noted that Petitioner's fairly conservative treatment course may have been influenced in part by his incarceration and (at least temporarily) by the Pandemic. Overall, there appears to be opportunity for the parties to reach a reasonable and prompt compromise on an appropriate pain and suffering award for Petitioner. If that is not possible, the case will likely be transferred out of SPU for further proceedings.

Accordingly, Petitioner shall file a status report updating on the progress made toward informally resolving damages by no later than Friday, July 12, 2024. The status report shall specify the date on which Petitioner conveyed or intends to convey a damages demand. If Petitioner's damages demand is ready for Respondent's consideration, the status report shall also specify the date on which Respondent provided his reaction. Otherwise, the parties shall confer, and Petitioner shall report the date by which Respondent expects to offer a counter-proposal.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master